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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,218	10/06/2000	G. Grady McBride	5259-04800	3182

7590 09/17/2003

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(C)
EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
3731	10

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/684,218	MCBRIDE ET AL.
	Examiner	Art Unit
	Julian W. Woo	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 108-186 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 108-123, 125-138, 140-165, 170-181, 183, 184 and 186 is/are rejected.
- 7) Claim(s) 124, 139, 166-169, 182 and 185 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6,7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 170-185 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 170, lines 7 and 11, "the first section" lacks antecedent basis. Also, the first and second elongated members are said to be "coupled to bone," which is claimed as an unpatentable, structural part of the invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 108-111, 113-118, 120, 170-174, and 176-181 are rejected under 35 U.S.C. 102(b) as being anticipated by Aebi et al. (5,047,029). With respect to claims 108, Aebi et al. disclose, in the figures, an adjustable connector comprising a first section (14), a second section (6), and a fastener (36), where the first section and the second section are allowed to move within a limited range of rotational motion relative to

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each other and where the fastener is configured (at 13c) to inhibit rotational movement of the first section relative to the second section. With respect to claim 109, the first and second sections are inhibited from being uncoupled by elements 9 and 15. With respect to claims 110 and 111, the first section comprises a collet (38), and the fastener comprises a collar (13). With respect to claims 113-118, figure 5 discloses the adjustable limits of the limited range of angulation of the first section relative to the second section, which is less than about 60 deg., about 0 deg., greater than 0 deg., less than about 90 deg., less than about 60 deg., or less than about 40 deg. With respect to claim 120, the first section comprises a fastening system (15, 16) for coupling the first section to an elongated member (4). With respect to claims 170-174, Aebi et al. disclose, in the manner of figure 1, a bone stabilization system with a first elongated member (4), a first fixation element (15), a second elongated member (5), a second fixation element (15), a connector (14) with first section (rotatable leaves 38a) and a second section (14a/b), and a fastener (36) configured to inhibit rotational movement of the first section relative to the second section; where the first section is a collet (38) and where the fastener includes a collar (13). With respect to claims 176-181, adjustable limit of the limited range of angulation of the first section relative to the second section, which is less than about 60 deg., about 0 deg., greater than 0 deg., less than about 90 deg., less than about 60 deg., or less than about 40 deg.

5. Claims 108, 109, 112-118, 120-123, 125-133, 135-138, 170-172, 175-181, 183, 184, and 186 are rejected under 35 U.S.C. 102(b) as being anticipated by Olerud (5,053,034). With respect to claims 108 and 125, Olerud discloses, in the figures, an

adjustable connector or a bone stabilization system comprising a first section (11), a second section (1), and a fastener (36), where the first section and the second section are allowed to move within a limited range of rotational motion relative to each other and where the fastener is configured to inhibit rotational movement of the first section relative to the second section. With respect to claims 109, 112, 126, and 127, the first and second sections are inhibited from being uncoupled by a setscrew (36). With respect to claims 113-118 and 128-133, col. 2, lines 30-34 disclose the adjustable limits of the limited range of angulation of the first section relative to the second section, which is less than about 60 deg., about 0 deg., greater than 0 deg., less than about 90 deg., less than about 60 deg., or less than about 40 deg. With respect to claims 120, 121, 135, 136, and 183, the first section comprises a fastening system or opening (13) for coupling the first section to an elongated member and an opening (at 15) for accepting a setscrew. With respect to claim 122, 137, and 184, the second section has a fastening system (3) for coupling to a second elongated member (22). With respect to claim 123 and 138, an elongated member (e.g., "screw spindles") and a second elongated member are unitary, contoured members. With respect to claims 170-172 and 175, Olerud discloses a bone stabilization system with a first elongated member (e.g., a screw spindle), a first fixation element (15), a second elongated member (22), a second fixation element (3), a connector with first section (11) and a second section (1), and a fastener (36) configured to inhibit rotational movement of the first section relative to the second section; where the fastener is a setscrew. With respect to claims 176-181, adjustable limit of the limited range of angulation of the first section relative to the

second section, which is less than about 60 deg., about 0 deg., greater than 0 deg., less than about 90 deg., less than about 60 deg., or less than about 40 deg. With respect to claim 186, col. 1, lines 12-35 disclose a method of attaching a connector ("a spinal joint") to a bone stabilization system.

6. Claims 140-151 are rejected under 35 U.S.C. 102(a) as being anticipated by Nichols et al. (2002/0052603). Nichols et al. disclose, in figures 8-15, an adjustable connector with a first section (22) having a hollow portion, a collet (22d), and a fastening system (42, 50); a second section (24) with a connecting member and a fastening system (44, 50), a collar (28), an elongated and a second elongated member (12, 14), and a compression instrument (70); where a range of rotational motion of the first section relative to the second section is limited to less than 360 deg., 90 deg., or 40 deg.; where the first section is inhibited from being removed from the second section, and where the distance between the fastening systems is adjustable.

7. Claims 108, 119, 125, 134, and 153-165 are rejected under 35 U.S.C. 102(b) as being anticipated by Allard et al (5,725,526). Allard et al. disclose, in the figures, a connector (20) for a bone stabilization having a first section with a holder (22) and a fastening system for an elongated member (3), a second section (10) having a connecting member (2), a lining (12), and a fastener (26), where the first section is configured to be adjustably angulated relative to the second section, where the range of angulation or rotation is limited to less than 90 deg., 40 deg., about 20 deg., or 60 deg., is about 0 deg., or is greater than 0 deg.

Allowable Subject Matter

8. Claims 124, 139, 166-169, 182, and 185 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an adjustable connector for attachment to an elongated member of a bone stabilization system that includes, *inter alia*, a first section and a fastening system, a second section rotatable relative to the first section and having a fastening system, and a fastener configured to inhibit rotation between the sections, where the distance between the fastening systems is adjustable. None of the prior art of record discloses a connector with, *inter alia*, a first section having a holder and a fastening system, a second section having a connecting member, and a lining between the connecting member and the holder, where fastening system has a setscrew and an opening configured to accept an elongated member. Also, none of the prior art of record discloses a bone stabilization system with, *inter alia*, first and second elongated members, first and second fixation elements, a connector with first and second sections rotatable relative to each other, and a lining between portions of the first and second sections.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Thomas, Jr. (6,110,173) teaches a connector for elongated members.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9302.



Julian W. Woo
Primary Examiner

September 10, 2003